UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC

EXHIBIT INDEX

PLAINTIFFS' RESPONSE TO BARD'S MOTION TO EXCLUDE THE OPINIONS OF ROBERT M. McMEEKING, PH.D.

Exhibit 1	McMeeking Deposition 7-6-17 Excerpts
Exhibit 2	Boresi & Sidebottom
Exhibit 3	Dieter & Schmidt
Exhibit 4	Briant Deposition 7-13-17 Excerpts
Exhibit 5	Briant Deposition 8-12-16 Excerpts
Exhibit 6	McMeeking Report 4-7-17 (**FILED UNDER SEAL**)
Exhibit 7	Brauer Deposition 5-23-14 Excerpts
Exhibit 8	K130366
Exhibit 9	K102511
Exhibit 10	K101431
Exhibit 11	K093659
Exhibit 12	K082305
Exhibit 13	K080668
Exhibit 14	K073090
Exhibit 15	K062887

Exhibit 16	K052578
Exhibit 17	K050558
Exhibit 18	K031328
Exhibit 19	K022236
Exhibit 20	BPV-17-01-00007760
Exhibit 21	BPV-17-01-00142912
Exhibit 22	BPVE-01-01081046 (**FILED UNDER SEAL**)
Exhibit 23	Moritz Deposition 7-18-17 Excerpts

EXHIBIT 8

K130366

DENALI® Filter System
510(k) Summary
21 CFR 807.92

MAY 15 2013

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2906

Fax: 480-449-2546

Contact: Joni Creal, Sr. Regulatory Affairs Specialist

Date: May 14, 2013

Subject Device Name

Device Trade Name:	**DENALI® Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK
Predicate Devices:	ECLIPSE® Filter System – Femoral and Jugular/Subclavian Delivery Kit (K101431; Clearance June 25, 2010)

Summary of Change

The ECLIPSE® Filter received FDA clearance under K101431 on June 25, 2010. As part of the product improvement life cycle, Bard Peripheral Vascular, Inc. (BPV) has chosen to re-design its vena cava filter platform. The new filter design is named the DENALI® Filter and incorporates cranial anchors, caudal anchors, penetration limiters and will be terminally electropolished. In addition, minor changes have been made to the IFU.

Device Description

The DENALI® Filter consists of twelve Nitinol appendages emanating from a central snareable tip. These twelve appendages (six legs and six arms) form two levels of filtration for emboli; the legs provide the lower level of filtration and the arms provide the upper level of filtration. Four out of the six legs have cranial anchors and the remaining two legs have caudal anchors. In addition, all of the legs have penetration limiters. The anchors have been designed to resist cranial and caudal migration, while allowing the filter to be percutaneously removed. The DENALI® Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The DENALI® Delivery Systems consist of an introducer sheath and dilator, and a preloaded DENALI® Filter in a storage tube with a pusher. The dilator accepts a 0.035" guidewire and allows for an 800 psi maximum pressure contrast power injection. Radiopaque marker bands are on the end of the dilator to aid in measuring the maximum indicated IVC diameter. They are spaced at a distance of 28 mm (outer-to-outer). The 55 cm, 8.4 French I.D. introducer sheath contains a radiopaque marker band at the distal tip and hemostasis valve with a side port. The pusher advances the filter through the introducer sheath to the pre-deployment mark and is then used to fix the filter in place while the filter is unsheathed.

Indications for Use of Device

The subject device, the DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kits, is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

DENALI® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Devices

The DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kit has the following similarities to its predicate device, the ECLIPSE® Filter System – Femoral and Jugular/Subclavian Delivery Kit (clearance to market via K101431 on June 25, 2010):

- Same intended use
- Same indications for use
- Similar filter and delivery system design
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Similar packaging configuration and materials
- Same sterility assurance level and method of sterilization

The differences between the subject device and its predicate device are as follows:

- Laser-cut filter from a Nitinol tube (single piece with welded snare tip)
- Caudal anchors
- Penetration limiters (one on each filter leg)
- Dimensional modifications
- Delivery System Modifications
- Updated IFU

The successful completion of the testing required per the risk assessment demonstrates that the technological characteristics and performance criteria of the DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kits are comparable to the predicate device and that the subject device can perform in a manner substantially equivalent to devices currently on the market for the same intended use.

Performance Testing – *In-Vitro* Testing

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated using the *in-vitro* testing as outlined below:

- ***In-Vitro - Filter***
  - Fatigue Resistance

- Corrosion Resistance
- Cranial Migration Resistance
- Caudal Migration Resistance
- Penetration Resistance (Radial force)
- Tensile
- Removal Force
- Clot Trapping
- Filter Tip Visibility (Radiopacity)
- MRI Compatibility

- ***In-Vitro – Delivery System***
  - Deployment Force
  - Deployment Accuracy
  - Arm/Leg Entanglement (Configuration)
  - Filter Centering (Tilt)
  - Simulated Use
  - Delivery System Tensile Strength
  - Delivery System Torque
  - Visual Inspection (Freedom from surface defects)
  - Delivery System Visibility (Radiopacity)
  - Dimensional Verification
  - Burst Pressure
- ***Biocompatibility, per ISO 10993 - Filter***
  - Cytotoxicity
  - Sensitization
  - Irritation - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Subacute Toxicity and Implantation
  - Genotoxicity
  - Hemocompatibility
- ***Biocompatibility, per ISO 10993 - Delivery System***
  - Cytotoxicity
  - Sensitization
  - Irritation – Irracutaneous Reactivity

- Acute systemic toxicity
- Hemocompatibility

Performance Testing – *In-Vivo* Testing

Two GLP compliant animal studies were performed in support of the DENALI® Filter System, one to assess the filter and one to assess the delivery systems.

To assess the filter, an animal study was performed with the primary objective of the study being to evaluate the retrievability of the DENALI® Filter in an ovine animal model following implantation periods of 4 and 12 weeks. Twelve (12) filter retrievals were evaluated for: 1) ease of removal (as assessed by a clinical evaluator) and 2) cava wall damage as assessed by venography, gross evaluation, and histopathology (in two separate subgroups - immediately post-euthanasia (0 week healing) and after an 8 week healing period). The secondary objectives of this study were to assess caval narrowing/stenosis, caval patency, extravasation, filter strut configuration, filter visibility under fluoroscopy, fracture, intimal irregularities, migration, penetration, perforation, thrombus and tilt.

To assess the delivery systems, an acute animal study in an ovine animal model was performed. The acute study validated the following attributes of 12 Femoral and 12 Jugular/Subclavian DENALI® Filter Systems:

- Dilator Visibility
- Dilator Marker Band Visibility
- Introducer Sheath Tip (Jugular) and Introducer Marker Band (Femoral) Visibility
- Dilator/Introducer Trackability
- Dilator/Introducer Pushability
- Aspiration
- Delivery System Trackability
- Delivery System Pushability
- Ease of Deployment (Deployment Force)
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm/Leg Entanglement

- Filter Visibility Under Fluoroscopy
- Snare Tip Visibility under Fluoroscopy
- Pusher Assembly Visibility Under Fluoroscopy

Based upon the performance assessment, all acceptance criteria were met and the DENALI® Filter System was deemed acceptable by clinical evaluators. Specifically to the retreivability animal study, all 12 filters were successfully removed with an acceptable retrieval force. In addition, based on clinical evaluation and confirmed by the pathologist there was no observed caval occlusion/thrombosis, no definitive IVC penetrations/perforations, no contrast extravasation from the IVC after filter removal, no significant filter tilting, and no hemodynamically significant caval stenosis. One death occurred following filter placement which the pathologist and attending veterinarian determined not to be device related.

The delivery systems were assessed by a clinical evaluator and the following delivery system attributes were found to be acceptable: dilator visibility, dilator marker band visibility, introducer sheath tip (Jugular), introducer markerband (Femoral) visibility, dilator/introducer trackability, dilator/introducer pushability, aspiration, delivery system (with Filter) trackability, delivery system (with Filter) pushability, ease of deployment (Deployment Force), deployment accuracy, filter centering (Tilt), arm/leg entanglement, filter visibility under fluoroscopy, snare tip visibility under fluoroscopy and pusher assembly visibility under fluoroscopy.

Performance Testing – Clinical Testing

A single-arm, prospective, multi-center clinical study was conducted to assess the safety of the DENALI® Filter as both a permanent and retrievable device. Clinical Success Placement (CSP) was defined as freedom from subsequent PE, filter embolization, caval occlusion, filter or procedure related death, insertion adverse events, and technical failure of placement. The pre-established performance goal was that the lower bound of the 95% confidence interval for the CSP was greater than 80%. Technical success of placement (TSP) was defined as deployment of the filter such that the physician judged the location to be suitable to provide sufficient mechanical protection against PE. Additionally, the secondary endpoints of recurrent PE, new or worsening DVT, filter migration, filter fracture and tilt were assessed at the six month visit or the one month post-retrieval visit.

One hundred seventy five (175) patients (107 males, 68 females) were enrolled at 20 investigational sites across the United States. The mean age was 56.7 ± 15.8 years (range 18 – 89 years). Eighty six (86) patients had their filter successfully retrieved.

Of the 175 patients who underwent DENALI® Filter placement, 95 had active thromboembolic disease (the presence of DVT or PE at the time of filter placement). Of these 95 patients, 63 had a contraindication to anticoagulation, 7 had a complication related to the use of anticoagulant medication, 8 had a failure of anticoagulation, and 17 had a filter placed without contraindication, complication or failure related to anticoagulant medication. Eighty (80) patients without active thromboembolic disease (neither DVT nor PE at the time of filter placement) were enrolled in the study.

Reasons for filter placement were as follows: Surgery (n=86, 49%), Trauma (n=41, 23%), Hypercoagulopathy (n=33, 19%), Cancer (n=7, 4%), Stroke (n=3, 2%) and Other (n=5, 3%).

Sixty nine (69) patients completed a six month visit. Longer term data was available in 21 patients at 12-month follow up and in one patient at 18-month follow up. The study will continue to follow all patients to 24 months or 1 month post retrieval, whichever comes first. Three (3) patients withdrew their consent, 3 were lost to follow up and 7 died from pre-existing conditions. An independent Clinical Events Committee (CEC) determined that no patient deaths were attributed to the filter device, or implant or retrieval procedures. This clinical experience will be updated in the IFU once the study is complete.

Table 1: Patient Accountability

	Eligible for Visit (N)	Visit Completed (N, %)	Retrieved	Reason Visit Not Completed				Events Occurring Before Next Visit		Pending Visit
				Death[1]	Lost to Follow-Up	Withdrawn	Missed Visit	Migration	Fracture	
Baseline/Implant	175	175	N/A	0	0	0	0	0	0	N/A
3 Months	128	114 (89%)	28	6	1	0	5	0	0	2
6 Months	88	69 (78%)[2]	32	1	1	3	5	0	0	9
12 Months	25	21 (84%)[3]	23	0	0	0	1	0	0	3
18 Months	4	1 (25%)	3	0	0	0	0	0	0	3
24 Months	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0
Retrieval	88	88	86	N/A	N/A	N/A	N/A	N/A	N/A	N/A
30 Days Post-Retrieval	86	68 (79%)[4]	N/A	N/A	1	N/A	N/A	N/A	N/A	8

[1] CEC adjudicated, not device related
[2] 69 patients completed the 6-month visit, 9 patients were retrieved in the 6-month visit window (6-months plus or minus 30 days)
[3] 1 patient was retrieved in the 12-month visit window (12-months plus or minus 30 days)
[4] 77 patients completed the 30 Day Post-Retrieval Visit, 9 of which occurred during the six month visit window. 68 patients completing the one month post-retrieval visit are reported in the table above to prevent assessment at the 6-month visit and one month post-retrieval visit.

TSP for the DENALI® Filter was 100%. CSP for the DENALI® Filter was 96.1% and the lower bound of the 95% confidence interval was 91.2%. It was concluded that the performance goal was successfully met. Mean placement procedure time was 17.5 minutes.

There were no findings of caval occlusion, filter fracture, cranial migration, caudal migration, filter tilt at placement, or filter tilt at retrieval. There were two (2) cases of symptomatic PE; neither of which caused patient death. There were five (5) cases of asymptomatic penetration; none of which had clinical sequelae. Three (3) cases of penetration were noted at implant and two (2) cases of penetration were noted at retrieval. Twelve (12) patients reported thirteen (13) cases of new or worsening DVT. There were ten (10) cases of new DVT and three (3) cases of worsening DVT. All 10 new DVTs reported were in those patients that had active disease at the time of implant, were considered to be hypercoagulable, or those that had orthopedic procedures on their lower extremities. All site-reported adverse events were adjudicated by the CEC.

Table 2: Complication Rates

Recurrent PE	2 / 139[1] (1.4%)
Caval Occlusion	0 / 137[2] (0%)
New DVT	10 / 137 (7.3%)
Worsening DVT	3 / 137 (2.2%)
Filter Fracture	0 / 137 (0%)
Cranial Migration	0 / 137 (0%)
Caudal Migration	0 / 137 (0%)
Filter Penetration at Placement	3 / 175 (1.7%)
Filter Penetration at Retrieval	2 / 88[3] (2.3%)
Filter Tilt at Placement	0 / 175 (0%)
Filter Tilt at Retrieval	0 / 88[3] (0%)

[1]The denominator of 139 includes 69 patients who completed the 6-month visit, 68 patients who reached the one month post-retrieval visit and 2 patients who had a reported PE outside of the 6-month visit or the one month post-retrieval visit
[2]All complication rates with a denominator of 137 include 69 patients who completed the 6-month visit and 68 patients who reached the one month post-retrieval visit
[3]88 patients had a retrieval visit with 86 successful retrievals

DENALI® Filter retrieval was attempted in 88 patients and successful in 86 patients (97.7%). In the two (2) unsuccessful retrieval cases, the snare was unable to engage the filter retrieval hook due to anatomical curvature. Mean filter indwell time was 136.2 ± 90.6 days (median 120.0 days, range 5 – 454 days). The right internal jugular vein was used in all retrieval procedures and mean procedure time was 21.9 minutes.

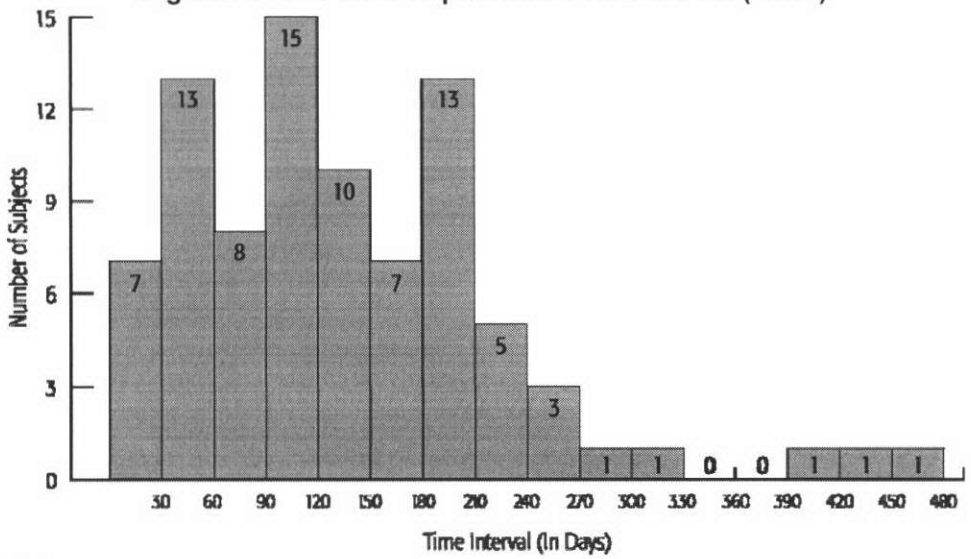
Venacavograms taken before and after the retrieval procedures of the IVC implant site revealed abnormalities that the CEC determined to be related to the device in two patients. One patient had minimal, self limited contrast extravasation post retrieval and another patient experienced intimal injury and caval narrowing of the IVC post retrieval. No clinical sequelae were reported for either patient.

Seventy seven (77) of the 86 patients who had their filter retrieved completed one month follow-up, one (1) subject was lost to follow-up, and eight (8) were pending. No instances of recurrent PE or new or worsening DVT were reported for any patient completing the one month post-retrieval visit.

Table 3: DENALI® Filter Retrieval Details

Number of Filter Retrieval Attempts	88
Number of Successful Retrievals	86
Retrieval Success Rate	97.7%
Mean Indwell Time	136.2 days
Maximum Indwell Time	454 days

Figure 3: Time from Implantation to Retrieval (N=86)



Conclusion

The DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kits are substantially equivalent to the legally marketed predicate device, the ECLIPSE® Filter System – Femoral and Jugular/Subclavian Delivery Systems (K101431).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

Bard Peripheral Vascular, Inc.
c/o Ms. Joni Creal
Regulatory Affairs Specialist II
1625 West Third Street
Tempe, AZ 85281

Re: K130366
Trade/Device Name: Denali Filter System – Femoral Delivery Kit and Jugular Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: February 14, 2013
Received: February 15, 2013

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130366

Device Name: DENALI® Filter System - Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The DENALI® Filter System - Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

DENALI® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
2013.05.15 12:22:13 -04'00'

EXHIBIT 9

MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kit
510(k) Summary
21 CFR 807.92

AUG 2 4 2011

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2906

Fax: 480-449-2546

Contact: Joni Creal, Regulatory Affairs Associate

Date: August 31, 2010

Subject Device Name:

Device Trade Name:	**MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit (MD800J)**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK
Predicate Devices:	ECLIPSE™ Filter System – Jugular/Subclavian Delivery Kit (K101431; Clearance June 25, 2010)

Summary of Change:

The primary modification to the predicate device, the ECLIPSE™ Filter System – Jugular/Subclavian Delivery System (K101431), compared to the subject device, the MERIDIAN™ Jugular/Subclavian Delivery System, is the addition of one downward pointing titanium anchor which is laser welded to each filter wire arm (6 total). In

addition, the Jugular delivery system has been modified to accommodate the filter design changes and minor changes have been made to the IFU.

Device Description:

The MERIDIAN™ Filter consists of twelve electropolished shape-memory nitinol wires emanating from a central electropolished nitinol filter hook. These 12 wires form two levels of embolic filtration: the six legs provide the lower level of filtration and the six arms provide the upper level of filtration. The legs contain hooks and the arms contain anchors to resist filter movement. The MERIDIAN™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The subject MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer sheath and dilator set and a delivery device preloaded with the MERIDIAN™ Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular approach using the Seldinger technique. The dilator accepts a 0.038" guidewire, enables a contrast medium power injection up to 800 psi maximum pressure, and is fitted with two radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip for identification of the distal end of the sheath and a hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and delivery mechanism to deploy the MERIDIAN™ Filter.

Indications for Use of Device:

The subject device, the MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit, is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Devices:

The technological characteristics of the subject device, the MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit, are substantially equivalent to those of the predicate device, the ECLIPSE™ Filter System –Jugular/Subclavian Delivery System (K101431), in terms of intended use, indications for use, application, user population, operating principle, delivery system design, filter bi-level design, fundamental scientific technology, packaging configuration, and sterilization method.

Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated using *in vitro* and *in vivo* testing performed as outlined below:

In Vitro

- Fatigue Resistance
- Anchor Weld Tensile Strength
- Cephalad Migration Resistance
- Caudal Migration Resistance
- Removal Force
- MRI Compatibility
- Delivery System Trackability
- Delivery System Pushability
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm/Leg Entanglement (Configuration)
- Biocompatibility
- Corrosion Resistance

In Vivo

- Retreivability
- Fatigue Resistance
- Cephalad Migration Resistance
- Caudal Migration Resistance
- Penetration Resistance
- Perforation
- Caval Patency
- Caval Damage
- Caval Narrowing
- Delivery System Trackability
- Delivery System Pushability
- Ease of Deployment (Deployment Force)
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm/Leg Entanglement (Configuration)
- Filter Visibility Under Fluoroscopy
- Delivery System Visibility Under Fluoroscopy

The results from these tests demonstrate that the technological characteristics and performance criteria of the MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit is comparable to the predicate device and that the subject device can perform in a manner substantially equivalent to devices currently on the market for the same intended use.

Conclusions:

The MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit is substantially equivalent to the legally marketed predicate device, the ECLIPSE™ Filter System – Jugular/Subclavian Delivery System (K101431).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bard Peripheral Vascular, Inc.
c/o Ms. Joni Creal
Regulatory Affairs Associate
1625 West Third Street
Tempe, AZ 85281

AUG 24 2011

Re: K102511
Trade Name: MERIDIAN Filter System – Jugular/Subclavian Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: June 27, 2011
Received: June 28, 2011

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kits

Indications for Use:

The MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use_X_ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102541

EXHIBIT 10

JUN 2 5 2010

ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2906

Fax: 480-449-2546

Contact: Joni Creal, Regulatory Affairs Associate

Date: June 21, 2010

Subject Device Name:

Device Trade Name:	**ECLIPSE™ Filter System – Femoral Delivery Kit (EC500F)** and **ECLIPSE™ Filter System – Jugular/Subclavian Delivery Kit (EC500J)**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK
Predicate Devices:	ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits (K093659)

Summary of Change:

The primary modification from the predicate device, the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery System (K093659), to the subject device, the ECLIPSE™ Femoral Filter System and Jugular/Subclavian Delivery System, was an addition of a Patient Brochure and Implant Card to the device labeling. In addition, a

kangaroo pouch was added to accommodate the Patient Brochure and Implant Card, and minor labeling modifications were made.

Device Description:

The ECLIPSE™ Filter consists of twelve electropolished shape-memory nitinol wires emanating from a central electropolished nitinol filter hook. These 12 wires form two levels of embolic filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The ECLIPSE™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The ECLIPSE™ Filter System – Femoral Delivery Kit consists of a 7 French inner diameter (I.D.) introducer catheter and dilator set and a storage tube preloaded with the ECLIPSE™ Filter and pusher system. The dilator is fitted with 2 radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The storage tube and pusher system attach to the introducer and allow for delivery and deployment of the ECLIPSE™ Filter.

The ECLIPSE™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer catheter and dilator set and a delivery device preloaded with the ECLIPSE™ Filter. The dilator is fitted with 2 radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and has a delivery mechanism to deploy the ECLIPSE™ Filter.

Indications for Use of Device:

The subject device, the ECLIPSE™ Filter Systems – Femoral and Jugular/Subclavian Delivery Kits, are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.

- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

ECLIPSE™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Devices:

The technological characteristics of the subject device, the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to those of the predicate device, the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery System (K093659), in terms of intended use, indications for use, application, user population, same operating principle, filter design, delivery system design, fundamental scientific technology, performance, and sterilization method.

Performance Testing Summary:

To demonstrate substantial equivalence of the subject device, the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits to the predicate device, the technological characteristics and performance criterion were evaluated using *in vitro* testing performed as outlined below:

- Packaging Testing
- Sterilization Testing
- Latex Testing

The results from these tests demonstrate that the technological characteristics and performance criteria of the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are comparable to the predicate device and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusions:

The ECLIPSE™ Filter Systems – Femoral and Jugular/Subclavian Delivery Kits are substantially equivalent to the legally marketed predicate device, the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery System (K093659).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 25 2010

Bard Peripheral Vascular, Inc.
c/o Joni Creal
Regulatory Affairs Associate
1625 West 3rd Street
Tempe, AZ 85281

Re: K101431
Trade Name: ECLISPE Filter System – Femoral Delivery Kit and ECLISPE Filter System – Jugular/Subclavian Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: June 21, 2010
Received: June 22, 2010

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Volkmer

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101431

Device Name: ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

ECLIPSE™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101431

EXHIBIT 11

ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

Submitter Information:

JAN 14 2010

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
PO Box 1740
Tempe, Arizona 85280

Phone: 480-638-2906

Fax: 480-449-2546

Contact: Joni Creal
Regulatory Affairs Associate

Subject Device:

Device Trade Name:	**ECLIPSE™ Filter System – Femoral Delivery Kit and ECLIPSE™ Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

G2 EXPRESS® Filter System – Femoral Delivery Kits (K082305)

G2 EXPRESS® Filter System –Jugular/Subclavian Delivery Kits (K082305)

Summary of Change:

The primary modification from the predicate device, the G2® EXPRESS Filter System – Femoral and Jugular/Subclavian Delivery System, to the subject device, the ECLIPSE™ Femoral Filter System and Jugular/Subclavian Delivery System, was an improvement of the surface finish of the filter raw material wire by electropolishing the wire prior to forming the filter. A cosmetic colorant modification to some of the molded components of the delivery kits was also made.

Device Description:

The ECLIPSE™ Filter consists of twelve electropolished shape-memory nitinol wires emanating from a central electropolished nitinol filter hook. These 12 wires form two levels of embolic filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The ECLIPSE™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The ECLIPSE™ Filter System – Femoral Delivery Kit consists of a 7 French inner diameter (I.D.) introducer catheter and dilator set and a storage tube preloaded with the ECLIPSE™ Filter and pusher system. The dilator is fitted with 2 radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The storage tube and pusher system attach to the introducer and allow for delivery and deployment of the ECLIPSE™ Filter.

The ECLIPSE™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer catheter and dilator set and a delivery device preloaded with the ECLIPSE™ Filter. The dilator is fitted with 2 radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and has a delivery mechanism to deploy the ECLIPSE™ Filter.

Indications for Use of Device:

The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- ECLIPSE™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to those of the predicate devices, the G2® EXPRESS Filter System – Femoral and Jugular/Subclavian Delivery System (K082305), in terms of intended use, indications for use, application, user population, same operating principle, basic design, fundamental scientific technology, performance, packaging configuration and sterilization method.

Conclusions:

The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits is substantially equivalent to the legally marketed predicate device, the G2® EXPRESS Filter System – Femoral and Jugular/Subclavian Delivery System Kits (K082305 – cleared October 31, 2008).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 14 2010

Bard Peripheral Vascular, Inc.
c/o Ms. Joni Creal
Regulatory Affairs Associate
1625 West Third Street
Tempe, AZ 85280-1749

Re: K093659
Trade/Device Name: ECLIPSE Filter System, Femoral and Jugular/Subclavian Delivery Kits
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: December 17, 2009
Received: December 18, 2009

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093659

Device Name: ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- ECLIPSE™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kelnar
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093659

EXHIBIT 12

K082305

G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

OCT 31 2008

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street PO Box 1740 Tempe, Arizona 85280
Phone:	480-303-2524
Fax:	480-449-2546
Contact:	Genevieve Balutowski Associate Project Manager, Regulatory Affairs

2. Subject Device:

Device Trade Name:	**G2 EXPRESS™ Filter System – Femoral Delivery Kit and G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

G2 EXPRESS™ Filter System – Femoral Delivery Kit (K080668)

G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit (K080668)

4. Summary of Change:

The modification from the predicate device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery System, to the subject device, the G2 EXPRESS™ Filter System Femoral and Jugular/Subclavian Delivery System, consisted of design improvements of the femoral and jugular/subclavian delivery kits.

5. Device Description:

The G2 EXPRESS™ Filter consists of 12 shape-memory nitinol wires emanating from a central nitinol sleeve with a snare tip. These 12 wires form two levels of emboli filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The G2 EXPRESS™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 Fr I.D. introducer sheath and dilator set and a delivery device preloaded with the G2 EXPRESS™ Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular approach. The delivery device fits within the introducer sheath and consists of a delivery mechanism to deploy the G2 EXPRESS™ Filter.

The G2® EXPRESS™ Filter System – Femoral Delivery Kit consists of a 7 Fr I.D. introducer catheter and dilator set and a storage tube preloaded with the G2 EXPRESS™ Filter and delivery device. The introducer sheath and dilator are used to gain access to the inferior vena cava via a femoral approach. The delivery device fits within the introducer sheath and consists of a delivery mechanism to deploy the G2 EXPRESS™ Filter.

6. Indication for Use of Device:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.

- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to those of the predicate devices, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits (K080668), in terms of intended use, indications for use, application, user population, basic design, fundamental scientific technology, performance, and sterilization method.

8. Conclusions:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits is substantially equivalent to the legally marketed predicate device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Bard Peripheral Vascular, Inc.
Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K082305
Trade/Device Name: G2 Express Filter System – Femoral and Jugular/Subclavian Delivery Kits
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: September 29, 2008
Received: September 30, 2008

Dear Ms. Balutowski:

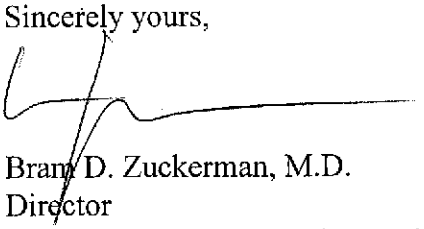
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use_X_____ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042265

EXHIBIT 13

K080668

G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street PO Box 1740 Tempe, Arizona 85280
Phone:	480-303-2524
Fax:	480-449-2546
Contact:	Genevieve Balutowski Associate Project Manager, Regulatory Affairs

JUL 30 2008

2. Subject Device:

Device Trade Name:	**G2 EXPRESS™ Filter System – Femoral Delivery Kit** and **G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Devices:

Recovery® G2® Filter System – Femoral Delivery Kit (K073090)

Recovery® G2® Filter System – Jugular/Subclavian Delivery Kit (K073090)

4. Summary of Change:

The modification from the predicate device, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery System, to the subject device, the G2 EXPRESS™ Filter System Femoral and Jugular/Subclavian Delivery System, was adding a snare to the tip of the filter. Additionally, minor dimensional modifications were made to the delivery systems to accommodate the snare tip.

5. Device Description:

The G2 EXPRESS™ Filter consists of 12 shape-memory nitinol wires emanating from a central nitinol sleeve with a snare tip. These 12 wires form two levels of emboli filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The G2 EXPRESS™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The G2 EXPRESS™ Filter System – Femoral Delivery Kit consists of a 7 French inner diameter (I.D.) introducer catheter and dilator set and a storage tube preloaded with the G2 EXPRESS™ Filter and pusher system. The introducer catheter and dilator are used to gain access to the inferior vena cava via a femoral approach using the Seldinger technique. The dilator accepts a 0.038" guidewire and the introducer catheter has two radiopaque marker bands on the distal end to assist in filter delivery. The pusher system is designed to pass through the introducer catheter.

The G2 EXPRESS™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer sheath and dilator set and a delivery device preloaded with the G2 EXPRESS™ Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular approach using the Seldinger technique. The dilator accepts a 0.038" guidewire and enables a contrast medium power injection up to 800 psi maximum pressure. The introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the G2 EXPRESS™ Filter.

6. Indication for Use of Device:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to those of the predicate devices, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits (K073090), in terms of intended use, indications for use, application, user population, basic design, fundamental scientific technology, performance, and sterilization method.

8. Conclusions:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits is substantially equivalent to the legally marketed predicate device, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2008

Bard Peripheral Vascular, Inc.
c/o Genevieve Balutowski, RAC
Associate Project Manager, Regulatory Affairs
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280

Re: K080668
Trade/Device Name: G2 Express Filter System – Femoral Delivery Kit and
G2 Express Filter System –Jugular/Subclavian Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: July 2, 2008
Received: July 3, 2008

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X AND/OR Over-The-Counter Use
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

~~Concurrence of CDRH, Office of Device~~ Evaluation (ODE)
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080668

EXHIBIT 14

Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kit
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

JAN 15 2008

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-303-2524
Fax:	480-449-2546
Contact:	Genevieve Balutowski Associate Project Manager, Regulatory Affairs

2. Subject Device:

Device Trade Name:	**Recovery® G2® Filter System – Femoral Delivery Kit** and **Recovery® G2 Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Devices:

G2™ Filter System – Femoral Delivery Kit (K062887)

G2™ Filter System – Jugular/Subclavian Delivery Kit (K052578)

4. Summary of Change:

The change to the predicate devices, G2™ Filter System – Femoral Delivery Kit and the G2™ Filter System – Jugular/Subclavian Delivery Kit, only affect the indications for use. Indications for use of the subject device, Recovery® G2® Filter System – Femoral and Jugular Delivery Kits, are identical to the indications for use of the predicate devices, with the exception of the last bullet point that notes:

"Recovery® G2® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal."

5. Device Description:

Recovery® G2® Filter System - Femoral and Jugular/Subclavian Delivery Kits

The Recovery® G2 Filter consists of 12, shape-memory nitinol wires emanating from a central nitinol sleeve. These 12 wires form two levels of emboli filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The Recovery® G2® Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm. The predicate device filter is identical to the subject device filter.

The Recovery® G2® Filter System – Femoral Delivery Kit consists of a 7 French I.D. introducer catheter and dilator set (Kit A) and a storage tube preloaded with the Recovery® G2® Filter and pusher system (Kit B). Kit A (introducer catheter and dilator) is used to gain access to the inferior vena cava via a femoral approach. The dilator accepts a 0.038" guidewire and the introducer catheter has 2 radiopaque marker bands on the distal end to assist in filter delivery. The pusher system (Kit B), designed to pass through the introducer catheter, consists of a grooved segment designed to hold and properly orient the filter legs and a flexible nitinol wire with a pad at the end that pushes on the filter apex.

The Recovery® G2® Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer sheath and dilator set and a delivery device preloaded with the Recovery® G2® Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular or subclavian approach. The dilator accepts a 0.038" guidewire and enables a contrast medium power injection up to 800 psi maximum pressure. The introducer sheath contains a radiopaque tip and hemostasis valve with a

side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the Recovery® G2® Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to properly orient the filter legs and contains a pusher wire consisting of a flexible nitinol wire with a pad at the end that pushes on the filter sleeve.

6. Intended Use of Device:

The subject device, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits, is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Recovery® G2® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

7. Performance Data:

The Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits were evaluated via data collected from bench and animal testing. Additionally, the safety of retrieval of the Recovery® G2® Filter was evaluated in a prospective, multi-center, non-randomized clinical study. Retrieval of the Recovery® G2® Filter was achieved in 95.1% of the study subjects undergoing a retrieval procedure. The mean filter indwell time in the retrieved subjects was 140.0 ± 62.1 days (median 143.5, range 5 – 300).

8. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to

those of the predicate devices, the G2® Filter System – Femoral Delivery Kit and the G2® Filter System – Jugular/Subclavian Delivery Kit, in terms of intended use, application, user population, basic design, fundamental scientific technology, performance, and sterilization method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 15 2008

Bard Peripheral Vascular, Inc.
c/o Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K073090
Trade Name: Recovery G2 Filter System – Femoral and Jugular/Subclavian Delivery Kits
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: October 31, 2007
Received: November 1, 2007

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073090

Device Name: Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Recovery® G2® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073090

Page 1 of 1

EXHIBIT 15

K062887

G2™ Filter System – Femoral Delivery Kit
510(k) Summary of Safety and Effectiveness
21 CFR 807.92

OCT 26 2006

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Phone: 480-303-2524

Fax: 480-449-2546

Contact: Genevieve Balutowski,
Senior Regulatory Affairs Specialist

2. Subject Device Name:

Device Trade Name:	**G2™ Filter System – Femoral Delivery Kit**
Common or Usual Name:	Vena Cava Filter
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

G2™ Filter System – Femoral Delivery Kit (K050558, cleared 8/29/05)

4. Summary of Change:

The design modification to the G2™ Filter System – Femoral Delivery Kit, as represented in this submission, is a modification to a component of the current delivery system. The G2™ Filter component of the subject device remains the same as the predicate device.

5. Device Description:

The G2™ Filter System – Femoral Delivery Kit consists of a 7 French inner diameter (I.D.) introducer catheter and dilator set (Kit A) and a storage tube preloaded with the G2™ Filter and pusher system (Kit B). Kit A (introducer catheter and dilator) is used to gain access to the inferior vena cava using the Seldinger technique. The dilator accepts a 0.038" guidewire and the introducer catheter has 2 radiopaque marker bands on distal end to assist in filter delivery. The pusher system (Kit B), designed to pass through the introducer catheter, consists a grooved segment designed to hold and properly orient the filter legs and a flexible nitinol wire with a pad at the end that pushes on the filter apex.

6. Intended Use of Device:

The G2™ Filter System – Femoral Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The subject device has the same intended use and indications of use as the predicate device, the G2™ Filter System - Femoral Delivery Kit (K050558, cleared 08/29/05).

7. Technological Comparison to Predicate Device:

The technological characteristics of G2™ Filter System – Femoral Delivery Kit are substantially equivalent to those of the predicate device, the G2™ Filter System – Femoral Delivery Kit, in terms of intended use, indication for use, application, user population, basic design, fundamental scientific technology, performance, and sterilization method.

8. Conclusions:

The G2™ Filter System – Femoral Delivery Kit met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The G2™ Filter System – Femoral Delivery Kit is substantially equivalent to the legally marketed predicate device, the G2™ Filter System – Femoral Delivery Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2006

Bard Peripheral Vascular, Inc.
c/o Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K062887
Trade Name: G2 Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: September 25, 2005
Received: September 26, 2005

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Furthermore, the indication for permanent placement of the G2 Filter System must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

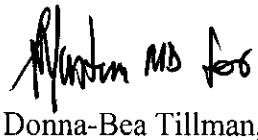
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under

the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062887

Device Name: G2™ Filter System – Femoral Delivery Kit

Indications for Use:

The G2™ Filter System – Femoral Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Donna R. Mahoney
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062887

EXHIBIT 16

NOV 25 2008

K052578

Appendix 4. Summary of Safety and Effectiveness

G2™ Filter System – Jugular/Subclavian Delivery Kit
510(k) Summary of Safety and Effectiveness
21 CFR 807.92.

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Phone: 480-303-2524

Fax: 480-449-2546

Contact: Genevieve Balutowski,
Senior Regulatory Affairs Specialist

2. Subject Device Name:

Device Trade Name:	**G2™ Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Vena Cava Filter
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

G2™ Filter System – Femoral Delivery Kit (K050558, cleared 8/29/05)

4. Summary of Change:

The design modification to the G2™ Filter System – Jugular/Subclavian Delivery Kit as represented in this submission is an additional delivery system. The G2™ Filter component of the subject device remains the same as the predicate device.

5. Device Description:

The G2™ Filter System – Jugular/Subclavian Delivery Kit allows for placement of the G2™ Filter via a Jugular or Subclavian vein approach. The G2™ Filter System – Jugular/Subclavian Delivery Kit consists of a dilator and introducer set and a delivery device with a preloaded filter. The dilator accepts a 0.038" guidewire and enables a contrast medium power injection up to 800 psi maximum pressure. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the G2™ Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to prevent leg entanglement.

6. Intended Use of Device:

The G2™ Filter System – Jugular/Subclavian Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The subject device has the same intended use and indications of use as the predicate device, the G2™ Filter System - Femoral Delivery Kit (K050558, cleared 08/29/05).

7. Technological Comparison to Predicate Device:

The technological characteristics of G2™ Filter System – Jugular/Subclavian Delivery Kit are substantially equivalent to those of the predicate device, the G2™ Filter System – Femoral Delivery Kit, in terms of intended use, indication for use, application, user population, basic design, performance, and sterilization method.

8. Conclusions:

The G2™ Filter System – Jugular/Subclavian Delivery Kit met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The G2™ Filter System – Jugular/Subclavian Delivery Kit is substantially equivalent to the legally marketed predicate device, the G2™ Filter System – Femoral Delivery Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2005

Bard Peripheral Vascular, Inc.
Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K052578
Trade Name: G2 Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: October 25, 2005
Received: October 26, 2005

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Furthermore, the indication for permanent placement of the G2 Filter System must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

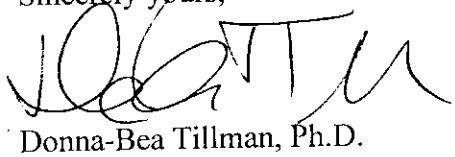
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: G2™ Filter System – Jugular/Subclavian Delivery Kit

Indications for Use:

The G2™ Filter System – Jugular/Subclavian Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vellucci

(Division Sign-Off)
Division of Cardiovascular Devices

Page 1 of 1

510(k) Number K052578

EXHIBIT 17

K050558
p 1 of 3

AUG 29 2005

Summary of Safety and Effectiveness

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

A. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Phone: 480-303-2539

Fax: 480-449-2546

Contact: Shari L. Allen, Director of Regulatory Affairs and Clinical Research

B. Subject Device Name: G2 Filter System

Common or Usual Name: Vena Cava Filter

Classification: Class II with Special Controls

The special controls for this device are compliant with the following:

- FDA's "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions", issued on November 26, 1999.
- BS EN 12006-3:1999 entitled, "Non-Active Surgical Implants - Particular Requirements for Cardiac and Vascular Implants - Part 3: Endovascular Devices".

C. Predicate Device

Device Name(s): Recovery Filter System (K022236, cleared 11/27/02)

Classification: Class II with Special Controls

D. Subject Device Description:

The G2 Filter System (subject) description is identical to the Recovery Filter System (predicate) description and indications for use. The modifications made to the predicate filter device and delivery system are primarily dimensional. No material changes or additional components have been incorporated.

The predicate filter device has been modified as a result of continued product improvement. The predicate delivery system has been modified to accommodate the geometry modifications of the predicate filter.

E. Statement of Intended Use for Subject Device:

The G2 Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

F. Substantial Equivalence:

The subject device has the following similarities to the predicate device that received clearance to market via K022236 on 11/27/02 and K031328 on 07/25/03:

- Same intended use;
- Same filter and delivery system materials;
- Same operating principle;
- Same fundamental scientific technology;
- Same packaging configuration and materials;
- Same sterility assurance level and method of sterilization.

The design, material, components, fundamental technology and intended use featured with the G2 Filter System are substantially equivalent to those featured with the predicate Recovery Filter System based on the design verification and validation activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2005

Bard Peripheral Vascular, Inc.
Shari Allen
Director of Regulatory Affairs and Clinical Research
P.O. Box 1740
Tempe, AZ 85280

Re: K050558
Trade Name: G2 Filter System
Regulation Number: 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II
Product Code: DTK
Dated: August 10, 2005
Received: August 11, 2005

Dear Ms. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Furthermore, the indication for permanent placement of the G2 Filter System must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

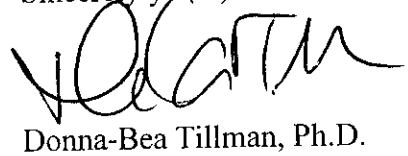
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050558

Indications For Use Statement

Device Name: G2 Filter System

Indications for Use: The G2 Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)0

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

EXHIBIT 18

JUL 2 5 2003

K031328

SECTION VIII

510(k) Summary of Safety and Effectiveness Information

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows:

A. Submitter Information:

Applicant:	Bard Peripheral Vascular, a division of C.R. Bard, Inc. 1625 West 3rd Street Tempe, Arizona 85280
Phone:	480-303-2640
Fax:	480-449-2546
Contact:	Mary Edwards, Vice-President

B. Device Name:

Trade Name:	Recovery Filter System
Common or Usual Name:	Percutaneous Vena Cava Filter
Classification Name:	Cardiovascular Intravascular Filter

C. Predicate Device Name(s): Recovery Filter System

D. Device Description:

The Recovery Filter System consists of a nitinol vena cava filter and a delivery system. The filter has two levels of filtration and is prepackaged in a storage tube. The delivery system consists of a 7 Fr ID introducer sheath and dilator and a pusher system. Both components of the system are packaged in Tyvek/film pouches.

E. Statement of Intended Use:

The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

-Pulmonary thromboembolism when anticoagulants are contraindicated.
-Failure of anticoagulant therapy for thromboembolic disease
-Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
-Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
-Recovery filter may be removed according to the instructions supplied in the Section labeled**: Optional Procedure for Filter Removal.** Data from removals in a 58 patient study suggests that the device can be safely removed (mean of 60 days; range 1-161 days).

F. Substantial Equivalence:

Recovery Filter is identical to the cited predicate device with the exception of the removal of labeling limitations and the addition of specific instructions to allow for safe removal of the device.

The safety of removal was addressed in a series of animal and clinical testing. The results of animal testing (including histology) and the confirmatory experience of 58 patients (mean 60 days to removal; range 1-161 days) show that the Recovery Filter may be safely retrieved and that the benefit of this procedure outweighs the potential associated risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Bard Peripheral Vascular
c/o Ms. Mary Edwards
Vice President, Regulatory & Clinical Affairs
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K031328
Bard® Recovery® Filter System RF-048F
Regulation Number: 21 CFR 870.3375
Regulation Name: Filter, Intravascular, Cardiovascular
Regulatory Class: Class II
Product Code: DTK
Dated: April 25, 2003
Received: April 28, 2003

Dear Ms. Edwards:

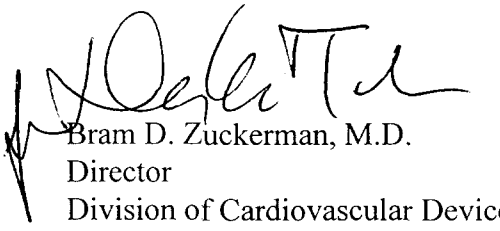
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT A

INDICATIONS FOR USE STATEMENT

Device Name: **Recovery Filter System**

Indications for Use:

The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
- Recovery filter may be removed according to the instructions supplied in the Section labeled: **Optional Procedure for Filter Removal.**

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031328

EXHIBIT 19

K022236

NOV 2 7 2002

IMPRA
A Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740
TEL: 800-321-4254
480-894-9515
FAX: 480-966-7062

IMPRA

510(k) SUMMARY OF SAFETY AND EFFECTIVENES INFORMATION

A. Submitter Information:

Submitter's Name: C.R. Bard, Inc., Impra
Submitter's Address: 1625 West 3rd Street
Contact Person: Kay Fuller
Contact Person's Telephone Number: (480) 303-2539
Contact Person's FAX Number: (480) 449-2546
Date of Preparation: July 8, 2002

B. Device Name:

Recovery™ Filter System

C. Predicate Devices:

Simon Nitinol Filter/Straightline™ System
Titanium Greenfield® Vena Cava Filter

D. Device Description:

The Recovery Filter System consists of a nitinol vena cava filter and a delivery system. The filter has two levels of filtration and is prepackaged in a storage tube. The delivery system consists of a 7 Fr ID introducer sheath and dilator and a pusher system. Both components of the system are packaged in Tyvek/film pouches.

E. Intended Use:

The Recovery Filter is indicated for use in the prevention of pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy in thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

F. Technological Characteristics Summary:

The filter consists of twelve, shape memory nitinol wires emanating from a central nitinol sleeve. The wires form two levels of filtration: six arms and six legs. The delivery system is used to place the filter into the inferior vena cava.

G. Performance Data:

Bench testing was performed per the FDA guidance document, "Guidance for Cardiovascular Intravascular Filter 510(k) Submission". Testing showed that the Recovery Filter is substantially equivalent to the Bard predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2002

Ms. Kay Fuller
Senior Regulatory Affairs Specialist
C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281

Re: K022236/S2
Trade/Device Name: Bard® Recovery™ Filter System, Model RF-048F
Regulation Number: 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II
Product Code: DTK
Dated: October 25, 2002
Received: October 29, 2002

Dear Ms Fuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the Recovery™ Filter for use as a retrievable or temporary filter have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

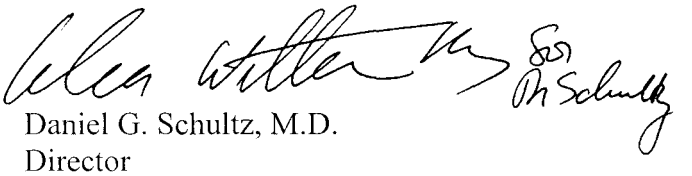
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022236

Device Name: Bard® Recovery™ Filter System, Model RF-048F

FDA's Statement of the Indications For Use for device:

The Recovery™ Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

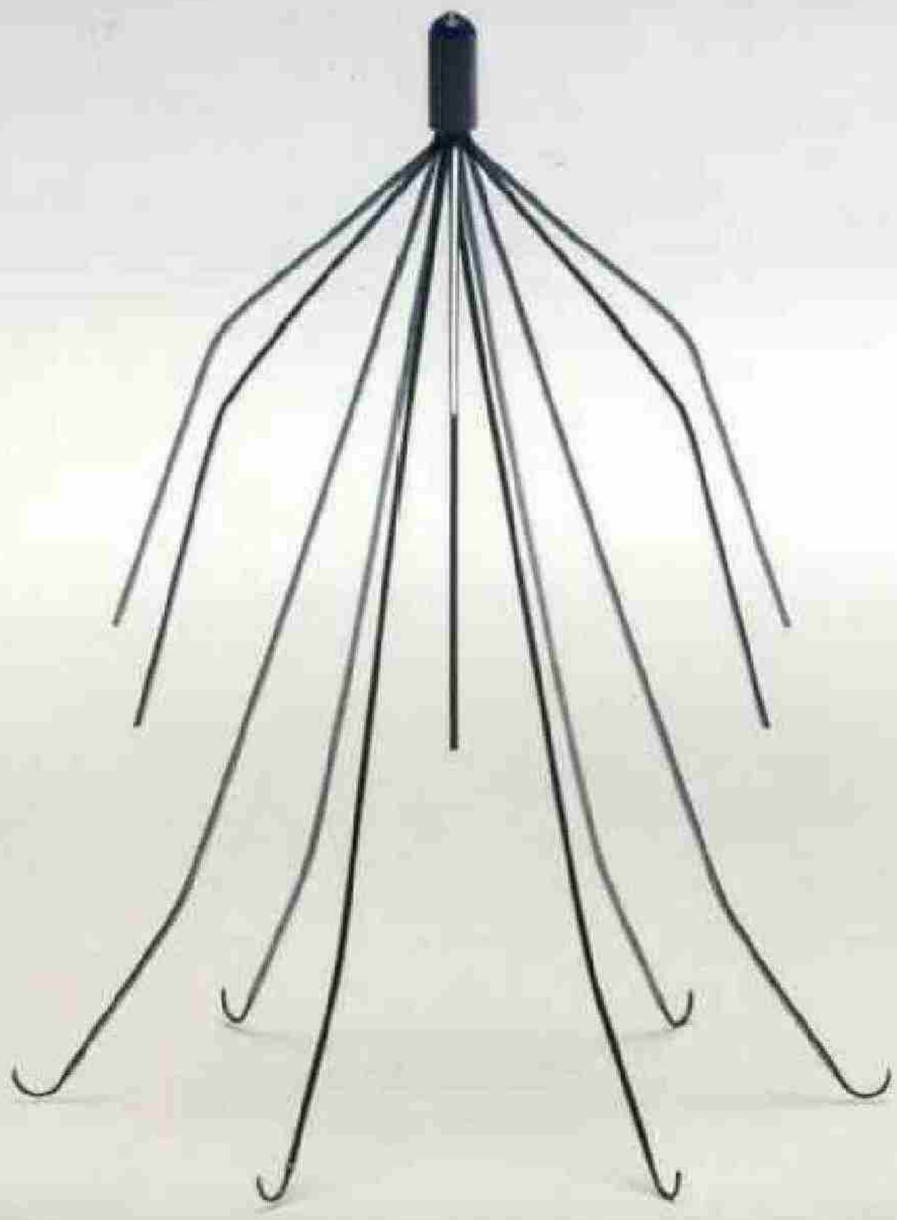
- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulation therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Division of Cardiovascular & Respiratory Devices
510(k) Number K022236

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

EXHIBIT 20

BARD
PERIPHERAL
VASCULAR



RECOVERY®

Timeless Performance™

Vena Cava Filter

DESIGNED TO BE THE ONLY FILTER
YOU WILL EVER NEED.

Bard established itself as a leader and innovator in the vena cava filter world with over 100,000 successful filter placements. Now, we have leveraged our decade-long experience to bring you the next-generation in filter performance. Introducing RECOVERY. A marked improvement over currently available devices,

RECOVERY® FILTER SYSTEM

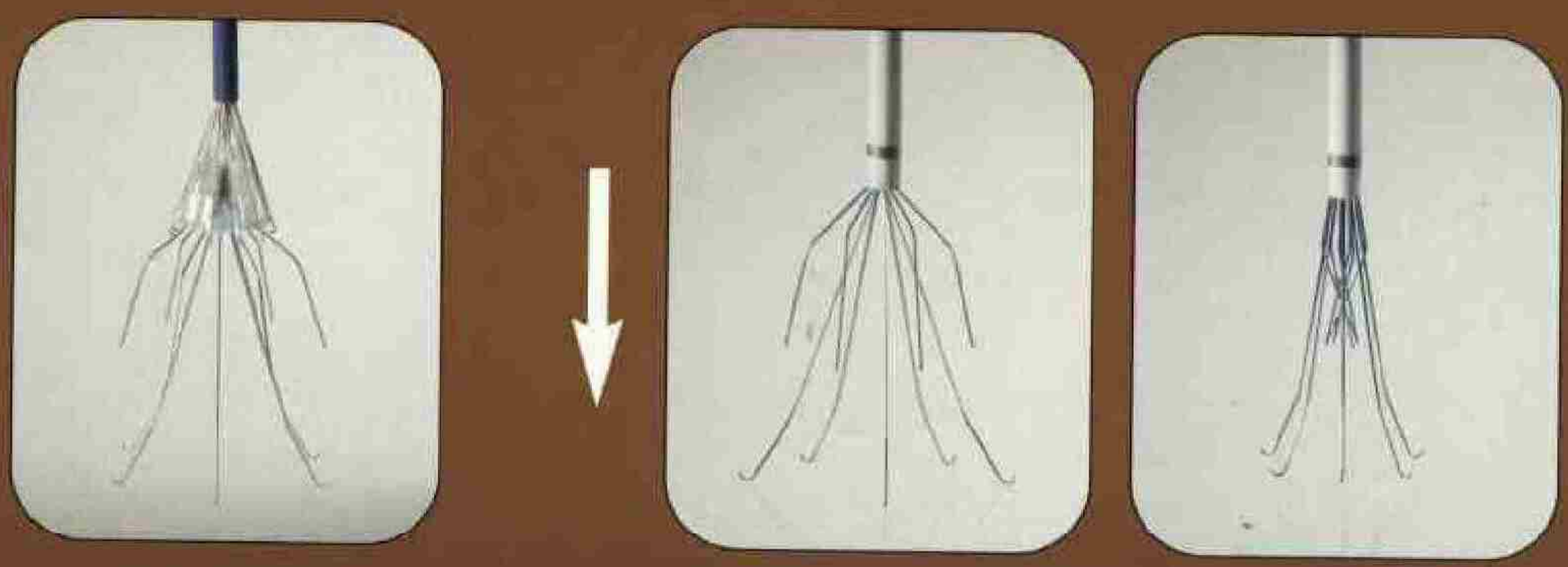
RECOVERY filter's unique self-centering design, proven conical shape and bi-level filtering system create the ideal balance between clot trapping efficiency and caval patency. Advanced design and accurate placement coupled with lasting performance make RECOVERY the permanent solution for caval interruption – possibly the only filter you will ever need.

The RECOVERY Cone Removal System was specifically designed to work with the RECOVERY Filter. The advanced engineering that went into developing the filter was

RECOVERY CONE® REMOVAL SYSTEM

used to create a system that provides a safe and easy retrieval, time after time.

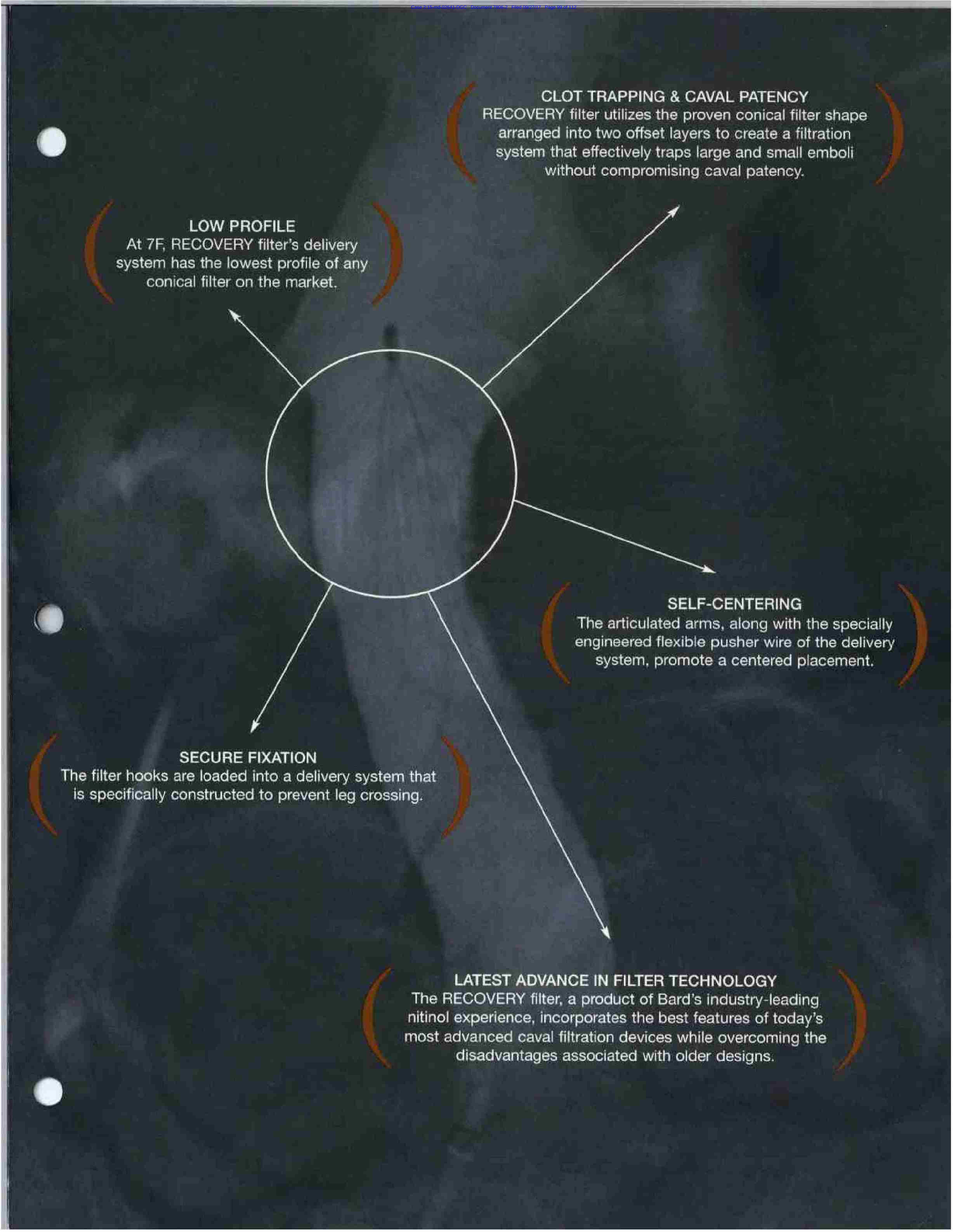
RECOVERY FILTER RETRIEVAL STEPS



Position the cone over the filter

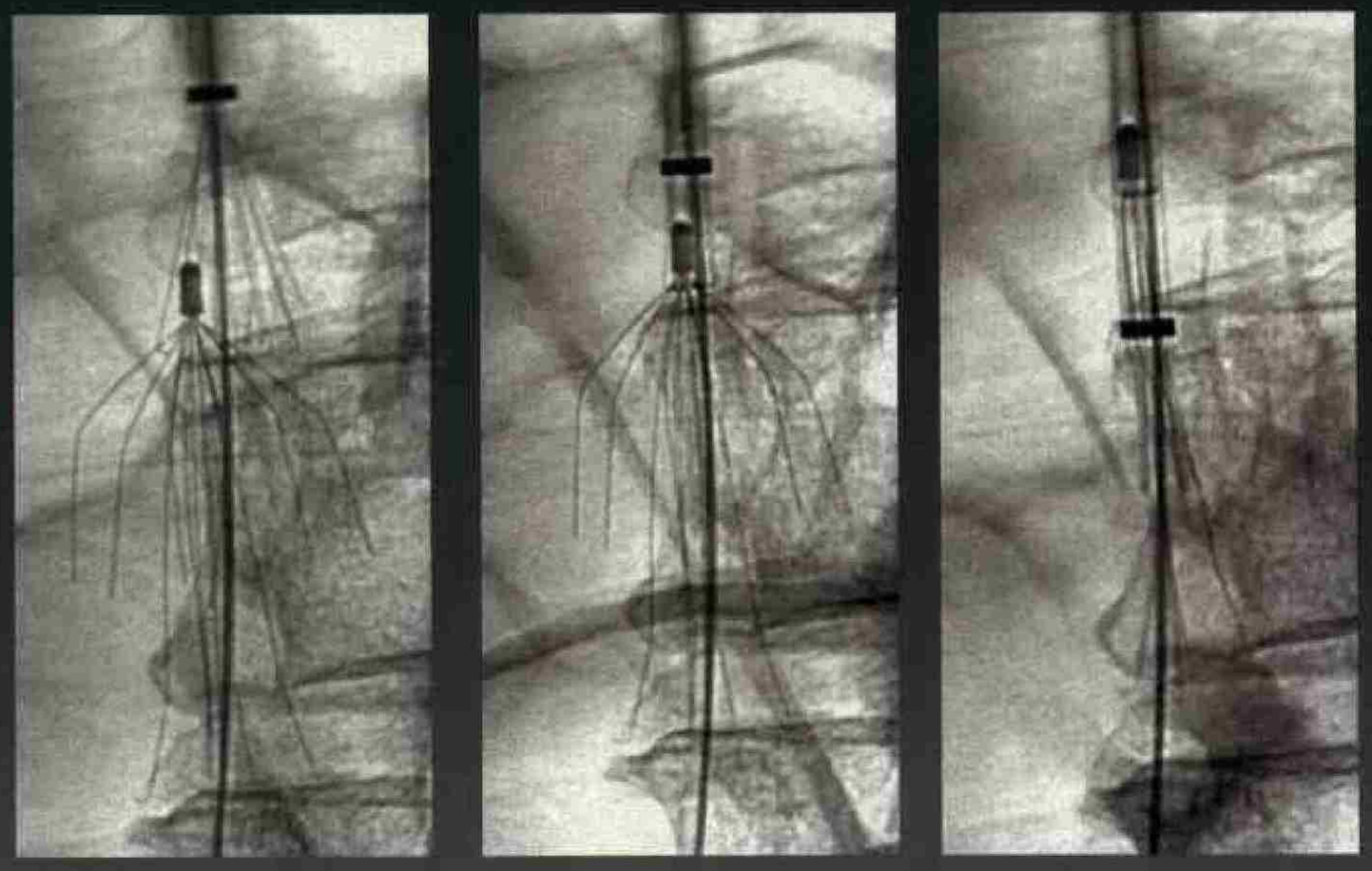
Advance the sheath to close the cone

Retract the filter into the cone


CLOT TRAPPING & CAVAL PATENCY
RECOVERY filter utilizes the proven conical filter shape arranged into two offset layers to create a filtration system that effectively traps large and small emboli without compromising caval patency.
LOW PROFILE
At 7F, RECOVERY filter's delivery system has the lowest profile of any conical filter on the market.
SELF-CENTERING
The articulated arms, along with the specially engineered flexible pusher wire of the delivery system, promote a centered placement.
SECURE FIXATION
The filter hooks are loaded into a delivery system that is specifically constructed to prevent leg crossing.
LATEST ADVANCE IN FILTER TECHNOLOGY
The RECOVERY filter, a product of Bard's industry-leading nitinol experience, incorporates the best features of today's most advanced caval filtration devices while overcoming the disadvantages associated with older designs.

ORDERING INFORMATION

CATALOG #	DESCRIPTION
RF-048F	Recovery® Filter – Femoral Delivery Kit
RC-15	Recovery Cone® Removal System



Bard Peripheral Vascular, Inc.
P.O. Box 1740
Tempe, AZ 85280-1740
USA
www.bardpv.com

Tel: 1.480.894.9515
1.800.321.4254

Fax: 1.480.966.7062
1.800.440.5376

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

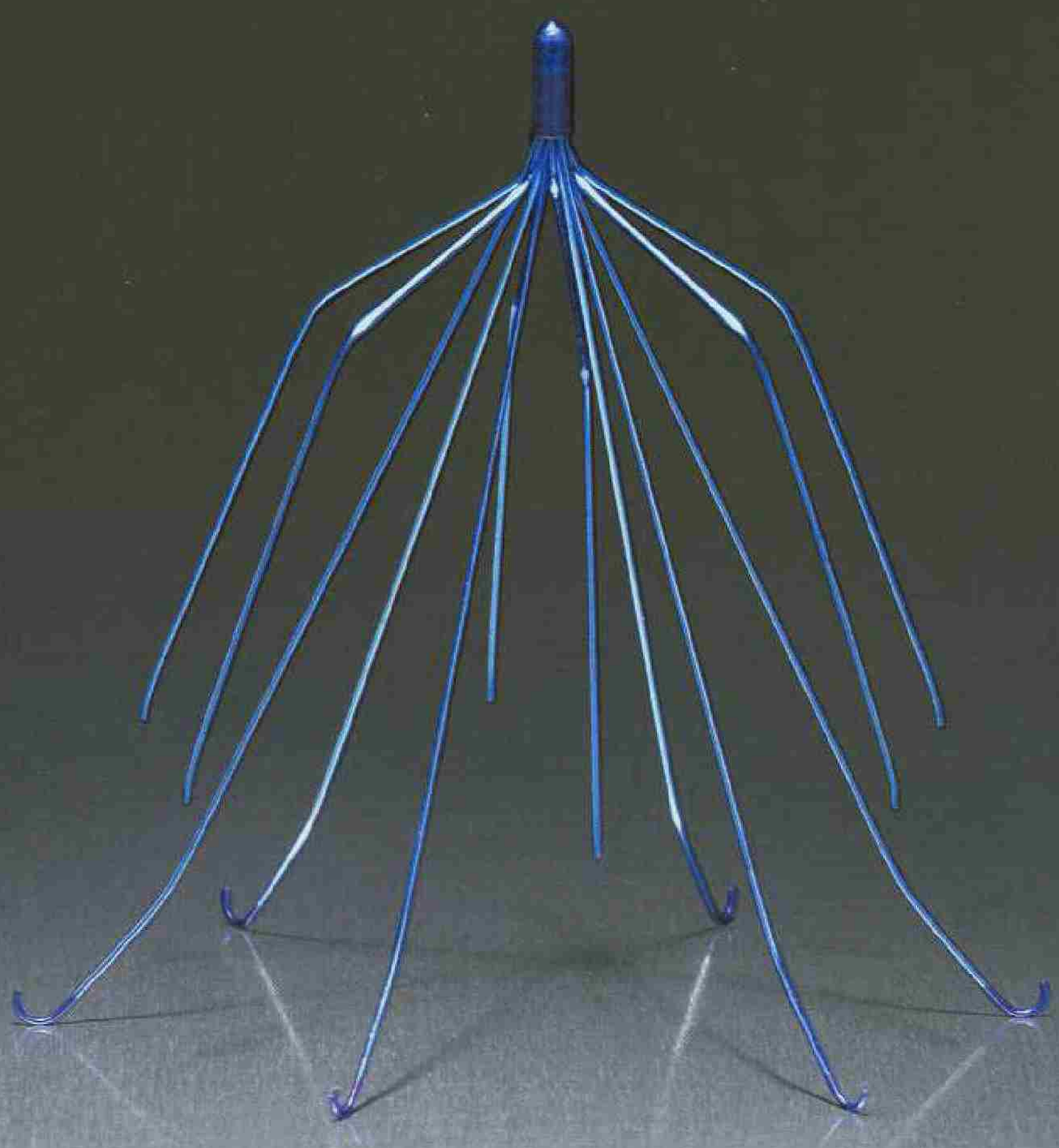
 S11436-

BARD PERIPHERAL VASCULAR

EXHIBIT 21

G2™ FILTER SYSTEM

for Permanent Placement



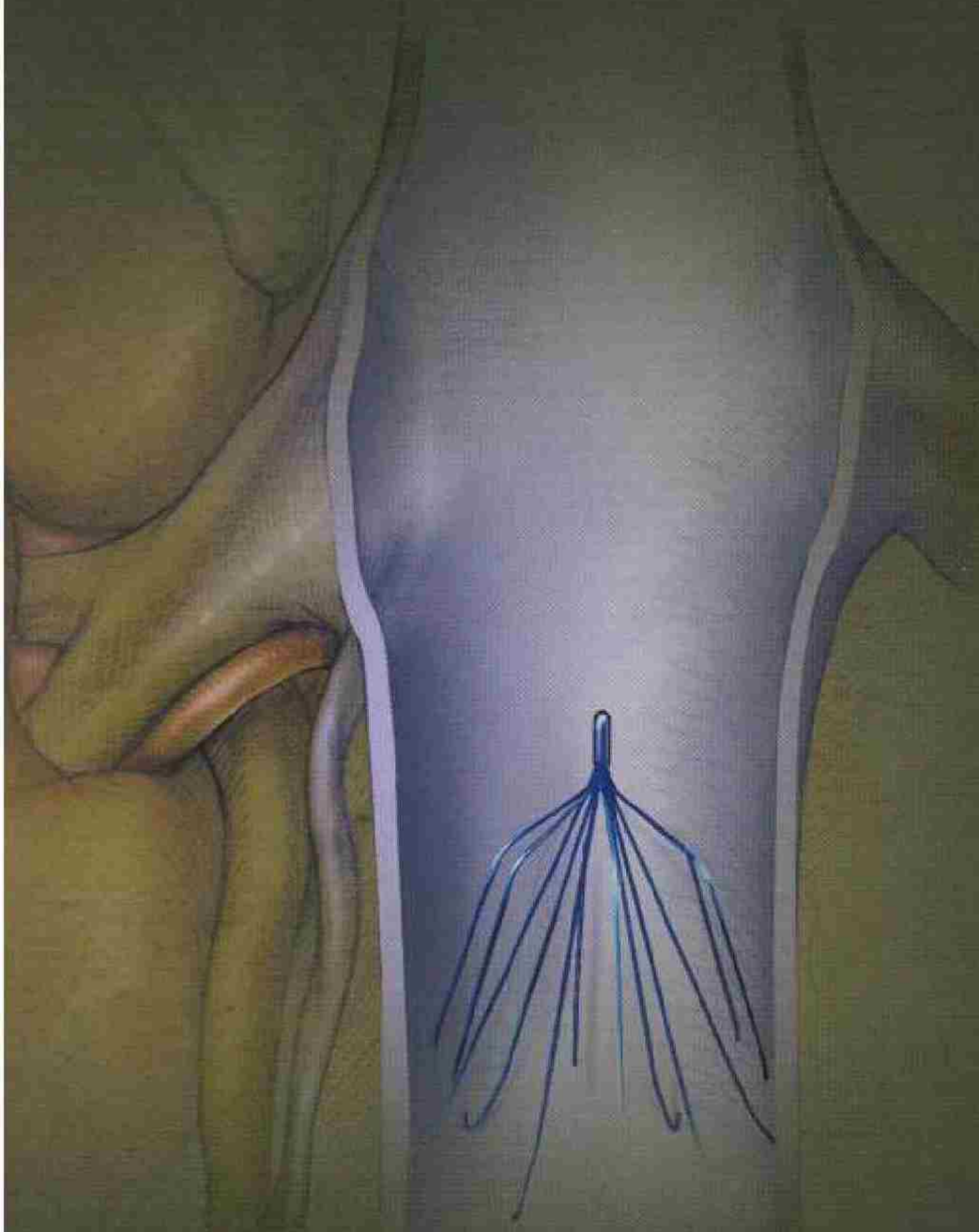
BARD
PERIPHERAL
VASCULAR

INTRODUCING THE

G2™

VENA CAVA FILTER

for Permanent Placement



The G2™ Filter combines the **best design features** of Bard's existing vena cava filters to create a **brand-new permanent filter platform** — taking strength and stability to a new level.

- Increased **MIGRATION RESISTANCE***
- **IMPROVED CENTERING***
- Enhanced **FRACTURE RESISTANCE***

The newly enhanced G2™ Filter continues the Bard tradition of filter **INNOVATION** spanning over a decade.

* Data on File

TIMELESS PE

CLOT TRAPPING & CAVAL PATENCY

G2™ Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

LOW-PROFILE

7F delivery system is the lowest profile of any conical filter on the market.

SECURE FIXATION

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2™ Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm
Data on File

SELF-CENTERING

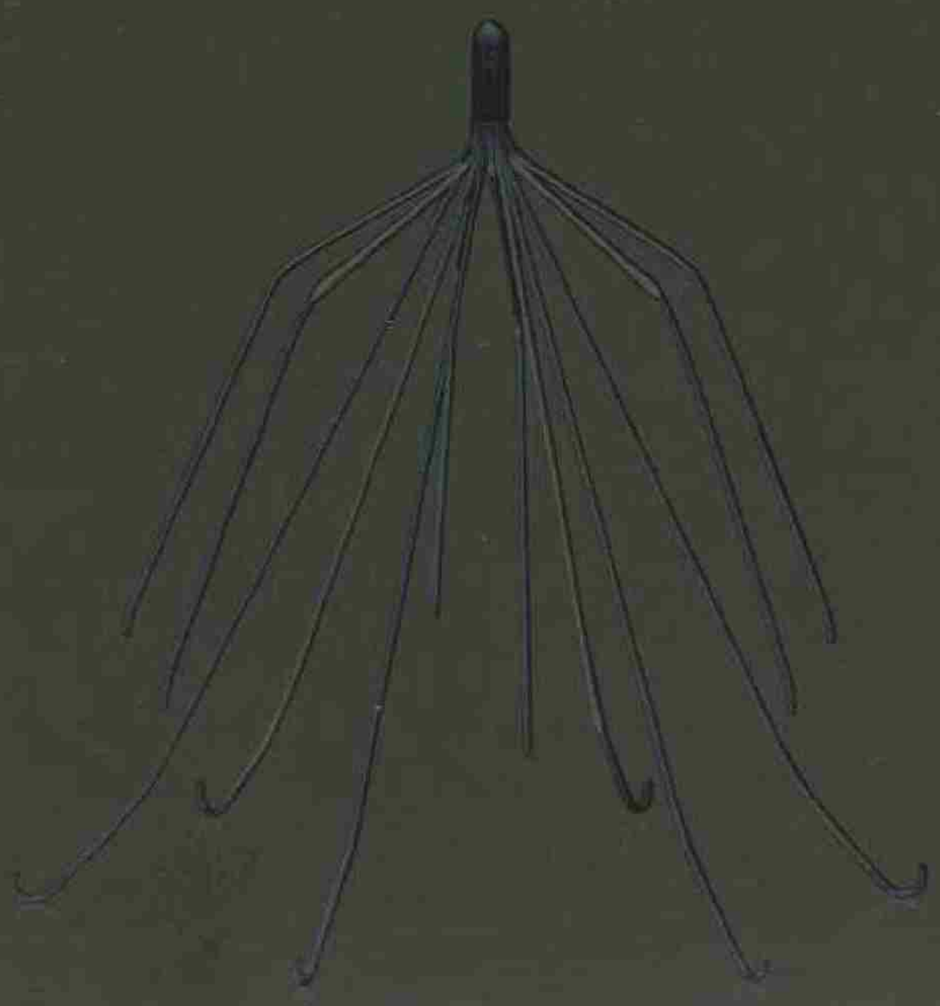
Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

RFORMANCE

G2™ FILTER SYSTEM

for Permanent Placement

ORDER INFORMATION



Catalog No.	Description
RF-310F	G2™ Filter System — Femoral Delivery Kit

PHYSICIAN'S SIGNATURE

For more information, contact:

Bard Peripheral Vascular, Inc.
P. O. Box 1740
Tempe, AZ 85280-1740
USA

Tel: 1-480-894-9515
1-800-321-4254
Fax: 1-480-966-7062
1-800-440-5376
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The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

 S11551-

BARD
PERIPHERAL VASCULAR

EXHIBIT 22
(Filed Under Seal)

EXHIBIT 23

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	:	NO. MD-15-02641-PHX-DGC

- - -

July 18, 2017

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of MARK W. MORITZ, M.D., taken pursuant to notice, was held at the offices McCarter & English, LLP, 100 Mulberry Street, Newark, New Jersey, beginning at 9:07 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES
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deps@golkow.com

of the medical community.

A. I don't recall them ever doing that.

Q. You just don't know as you sit here today?

MR. BROWN: Object to the form.

THE WITNESS: I don't -- I don't recall. I don't remember them ever doing that.

BY MR. O'CONNOR:

Q. You say at the bottom of Page 4 -- Page 4, "The use of retrievable filters is, therefore, based on the intent to some day remove it, although clinicians can decide to leave the filters in place permanently."

Now, did I read that correctly?

A. You did.

Q. And we talked about this earlier. But you knew that the Recovery, the G2, G2X, the Eclipse, and the Bard filters after that, Meridian and Denali,

were at least marketed as permanent filters, fair?

A. I believe that's correct.

Q. And when we talk about how they behave, if they should be as safe and effective, substantially equivalent to the predicate device, it would be the expectation of you as a member of the medical community that the Recovery, for example, would behave in the same fashion as a Simon Nitinol filter, fair?

MR. BROWN: Object to the form.

BY MR. O'CONNOR:

Q. That's a reasonable expectation?

A. That's a --

MR. BROWN: Object to the form.

THE WITNESS: That's a reasonable expectation.

BY MR. O'CONNOR:

Q. All right. There are patients who have indications for

permanent filters?

A. Yes.

Q. And your understanding is that when Bard marketed its filters, the so-called optional filters, that they were marketing that those filters could be used in patients with permanent indications?

A. Yes.

Q. Meaning the filter should last the lifetime of the patient?

A. Yes.

Q. Remain in place where it was implanted?

A. Yes.

Q. You found that wasn't the case?

A. I've seen filters that have tilted or migrated.

Q. And the literature indicates that Bard filters had tilted and migrated and did not behave like permanent filters, fair?

MR. BROWN: Object to the

BY MR. O'CONNOR:

Q. At Page 5, you talk about timing of retrieval. You haven't received any Bard documents. So I take it you're not aware of any Bard internal document that would speak to, if any exist, to the timing of retrievable of its filters?

A. That's correct.

Q. But you do know that Bard has consistently represented that the Recovery, the G2, G2X, the Eclipse were designed to be permanent filters?

A. I'm aware of that.

Q. And when you talk about issues of timing of retrieval, you are talking about removing a filter, among other things, before it has an opportunity to fail; is that fair?

A. That's fair.

MR. BROWN: Object to the form.

BY MR. O'CONNOR:

Q. In other words, there's a